

The Luxembourg Institute of Health and Advanced Biological Laboratories develop joint diagnostic solutions to measure neutralizing antibodies against SARS-CoV-2 variants

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The Luxembourg Institute of Health (LIH) and Advanced Biological Laboratories (ABL) are joining forces to predict immune protection against COVID-19 and support long-term vaccination strategies. To this end, the two laboratories have signed a license agreement and a collaboration agreement to provide two in vitro diagnostic solutions to measure neutralizing antibody levels.

LIH has established a reference viral neutralization assay that measures the activity of neutralizing antibodies against the different SARS-CoV-2 Variants of Concerns. This assay, realized in a BSL3 laboratory, is the reference assay to provide neutralization titers and predict immune protection against COVID-19 or disease severity. To rationalize long-term COVID vaccination strategies, LIH has also developed a more accessible surrogate variant neutralisation test, which measures neutralizing antibodies binding reflecting their neutralization activities.

This R&D collaboration proposes to establish a service-based product at LIH with the reference variant neutralization assay and to manufacture the surrogate variant neutralisation test for in vitro testing of the neutralization capacity of antibodies against different SARS-CoV-2 variants.

Seeking an accurate diagnostic solution to predict immune protection

Immunity to SARS-CoV-2 induced by natural infection or vaccination reduces the risk of severe infection and affords a degree of protection against reinfection. "It is now clear that neutralizing serum antibodies contributes mainly to this protective role" says Dr Carole Devaux, head of the HIV-Clinical and Translational Research (HIV-CTR) group. "The effectiveness and the duration of protective immunity is challenged by the spread of highly transmissible viral variants that evade vaccine or monoclonal antibodies protection. It is now critical to propose standardized and sensitive tests to assess SARS-CoV-2 immunity and guide vaccination strategies at the personal level "

At LIH, Dr Danielle Perez Bercoff has set-up the reference viral assay used to predict vaccine efficacy in different clinical trials. However, there are few standardized and accurate serological in vitro tests, to date, able to predict the neutralizing activities of antibodies, and available for the different variants of concern. Dr Eveline Santos da Silva and Dr Danielle Perez Bercoff will be in charge at LIH to optimize the surrogate variant neutralization test for this purpose. The collaboration with ABL aims to make a Prove of Concept of the feasibility of such market and to manufacture the surrogate variant neutralisation test.

Pertinent innovation for the health sector

Chalom Sayada, CEO and founder of ABL, adds: "We have been developing web and software-based diagnostic solutions for healthcare for more than 20 years now. Our focus has been on infectious diseases such as HIV, hepatitis and HPV, where we have built a global customer base. With COVID-19, we expanded our operations with the development and CE IVD registration of robust qPCR and Next Generation Sequencing assays for SARS-CoV-2 detection and variants identification, and now look forward to developing innovation for people with one of Luxembourg's leading healthcare players."

Helping to quickly roll out efficient measures

The relevance of the project is also central for LIH: "Such a partnership with ABL is extremely valuable for us. As part of our new strategy, we aim to have an impact that positively affects the lives of the patients and this partnership puts us in a position where we can effectively do that," adds Ulf Nehrbass, CEO of LIH.

A long time collaboration has been established between the research group HIV-CTR and ABL (SPREAD database, subtyping tool COMET) and new service agreements for SARS-CoV2 diagnostics were started in 2020 to support the R&D of ABL. Together with ABL, the research group speculated that a sensitive viral assay able to quantify the neutralizing titers against most VoCs and a surrogate variant neutralization test would be essential for the clinical management of patients in real-time to help to stratify

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the patients for the different vaccines, especially towards the outgrowth of the VOCs.

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About Advanced Biological Laboratories (ABL SA)

Improving Disease Management

Advanced Biological Laboratories (ABL), S.A., is a medical diagnostics company founded in 2000 as a separate spin-off from CRP-Santé (<https://www.lih.lu/>) Luxembourg.

ABL's products are marketed towards infectious disease clinicians, virology, and microbiology laboratories, including

- genotyping kits (within ABL France) and software for accredited laboratories (ISO 15189), mainly for microbiology applications (related to HIV, SARS-CoV-2, tuberculosis, HCV, HBV, HPV, CMV, influenza, 16s rRNA, etc.) for genotyping by capillary or high-throughput sequencing (DeepChek®), detection and quantification of DNA and RNA (UltraGene®)
- clinical software applications for infectious disease units.

computer dashboards and aggregation applications for research and clinical management.

ABL acquired the rights to all EVIVAR MEDICAL's viral hepatitis B & C assets in 2013 and a custom-made electronic medical record system for infectious diseases from GlaxoSmithKline in 2016. In July 2018, ABL acquired CDL Pharma to develop related CRO services and diagnostic kit manufacturing. In June 2019, ABL established its US subsidiary (AdvancedDx Biological Laboratories) covering the entire North American territory. This subsidiary markets ABL products for Research Use Only (RUO) and Investigational Use Only (IUO), as well as ABL products already registered with the FDA.

ABL acquired on October 15th, 2021 a controlling stake in ETABLISSEMENTS FAUVET GIREL, a company listed on Euronext Paris (Compartment C) which has not been active since 2018, with the aim to develop new activities in the field of genotype-based diagnosis of infectious diseases.

<http://www.fauvet-girel.fr/>

ABL offers a comprehensive suite of healthcare management products including Nadis®, TherapyEdge®, ViroScore®, SeqHepB, DeepChek®, UltraGene®, VisibleChek®, HepatiC®, BacterioChek and MicrobioChek used for the management, tracking and personalization of patient data. Since 2012, some ABL products are CE-IVD marked. In 2020, ABL obtained the CE-IVD mark for its DeepChek®-HIV tests as well as for its UltraGene® Combo2Screen SARS-CoV-2 test, its UltraGene® SARS-CoV-2 Multi Variants Deletions V1 test, its UltraGene® Triplex test and its UltraGene® Duplex SARS-CoV-2 test.

The other products are currently available for research purposes only.

For more information, visit www.ablsa.com.

About the Luxembourg Institute of Health (LIH)

The Luxembourg Institute of Health (LIH) is a public biomedical research organization focused on precision health and invested in becoming a leading reference in Europe for the translation of scientific excellence into meaningful benefits for patients.

LIH places the patient at the heart of all its activities, driven by a collective obligation towards society to use knowledge and technology arising from research on patient derived data to have a direct impact on people's health. Its dedicated teams of multidisciplinary researchers strive for excellence, generating relevant knowledge linked to immune related diseases and cancer.

The institute embraces collaborations, disruptive technology and process innovation as unique opportunities to improve the application of diagnostics and therapeutics with the long-term goal of preventing disease.

For more information, visit: www.lih.lu

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